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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,838	10/14/2005	Nobutaka Fujii	FUJII8	2131

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EXAMINER	
HA, JULIE	
ART UNIT	**PAPER NUMBER**
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	02/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,838	FUJII ET AL.	
	Examiner	Art Unit	
	Julie Ha	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 14, 31-32 and 18 and 39, drawn to a pharmaceutical composition comprising a peptide with the formula X-DLys-Pro-Tyr-Arg-Cit-Cys-Arg, and a method for preventing or treating chronic rheumatoid arthritis in subjects by administering to the subject a pharmaceutical composition comprising as an active ingredient a therapeutically effective amount of a peptide.

Group 2, claim(s) 14 and 31, drawn to a pharmaceutical composition comprising a peptide with the formula X-DCit-Pro-Tyr-Arg-Cit-Cys-Arg.

Group 3, claim(s) 14 and 31, drawn to a pharmaceutical composition comprising a peptide with the formula X-DLys-Pro-Tyr-Cit-Cit-Cys-Arg.

Group 4, claim(s) 14 and 31, drawn to a pharmaceutical composition comprising a peptide with the formula X-DCit-Pro-Tyr-Cit-Cit-Cys-Arg.

Group 5, claim(s) 14, 31 and 32, drawn to a pharmaceutical composition comprising a peptide with the formula X-DGlu-Pro-Tyr-Arg-Cit-Cys-Arg.

Group 6, claim(s) 14 and 31, drawn to a pharmaceutical composition comprising a peptide with the formula X-DLys-Pro-Glu-Cit-Cys-Arg.

Group 7, claim(s) 14 and 31, drawn to a pharmaceutical composition comprising a peptide with the formula X-DGlu-Pro-DGlu-Arg-Cit-Cys-Arg.

Group 8, claim(s) 14 and 31, drawn to a pharmaceutical composition comprising a peptide with the formula X-DGlu-Pro-Tyr-DGlu-Cit-Cys-Arg.

Group 9, claim(s) 14 and 31, drawn to a pharmaceutical composition comprising a peptide with the formula X-DGlu-Pro-DGlu-Arg-Cit-Cys-Arg.

Group 10, claim(s) 18 and 33-40, drawn to a method of treating cancer using a peptide with the formula X-DLys-Pro-Tyr-Arg-Cit-Cys-Arg.

Group 11, claim(s) 18 and 39-40, drawn to a method of treating cancer using a peptide with the formula X-DCit-Pro-Tyr-Arg-Cit-Cys-Arg.

Group 12, claim(s) 18 and 39, drawn to a method of treating cancer using a peptide with the formula X-DLys-Pro-Tyr-Cit-Cit-Cys-Arg.

Group 13, claim(s) 18 and 39, drawn to a method of treating cancer using a peptide with the formula X-DCit-Pro-Tyr-Cit-Cit-Cys-Arg.

Group 14, claim(s) 18 and 39-40, drawn to a method of treating cancer using a peptide with the formula X-DGlu-Pro-Tyr-Arg-Cit-Cys-Arg.

Group 15, claim(s) 18 and 39, drawn to a method of treating cancer using a peptide with the formula X-DLys-Pro-Glu-Cit-Cys-Arg.

Group 16, claim(s) 18 and 39, drawn to a method of treating cancer using a peptide with the formula X-DGlu-Pro-DGlu-Arg-Cit-Cys-Arg.

Group 17, claim(s) 18 and 39, drawn to a method of treating cancer using a peptide with the formula X-DGlu-Pro-Tyr-DGlu-Cit-Cys-Arg.

Group 18, claim(s) 18 and 39, drawn to a method of treating cancer using a peptide with the formula X-DGlu-Pro-DGlu-Arg-Cit-Cys-Arg.

Group 19, claim(s) 18 and 39, drawn to a method of treating chronic rheumatoid arthritis using a peptide with the formula X-DCit-Pro-Tyr-Arg-Cit-Cys-Arg.

Group 20, claim(s) 18 and 39, drawn to a method of treating chronic rheumatoid arthritis using a peptide with the formula X-DLys-Pro-Tyr-Cit-Cit-Cys-Arg.

Group 21, claim(s) 18 and 39, drawn to a method of treating chronic rheumatoid arthritis using a peptide with the formula X-DCit-Pro-Tyr-Cit-Cit-Cys-Arg.

Group 22, claim(s) 18 and 39-40, drawn to a method of treating chronic rheumatoid arthritis using a peptide with the formula X-DGlu-Pro-Tyr-Arg-Cit-Cys-Arg.

Group 23, claim(s) 18 and 39, drawn to a method of treating chronic rheumatoid arthritis using a peptide with the formula X-DLys-Pro-Glu-Cit-Cys-Arg.

Group 24, claim(s) 18 and 39, drawn to a method of treating chronic rheumatoid arthritis using a peptide with the formula X-DGlu-Pro-DGlu-Arg-Cit-Cys-Arg.

Group 25, claim(s) 18 and 39, drawn to a method of treating chronic rheumatoid arthritis using a peptide with the formula X-DGlu-Pro-Tyr-DGlu-Cit-Cys-Arg.

Group 26, claim(s) 18 and 39, drawn to a method of treating chronic rheumatoid arthritis using a peptide with the formula X-DGlu-Pro-DGlu-Arg-Cit-Cys-Arg.

Linking Claims

2. Claim 1-3, 5, 7-10 and 15 link(s) inventions 1-9 and claim 17 link(s) inventions 1 and 10-26. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 1-3, 5, 7-10, 15 and 17. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is

withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. The inventions listed as Groups 1-26 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature recited in Group I is peptides sharing a common core of the formula X-DLys-Pro-Tyr-Arg-Cit-Cys-Arg and a method for preventing or treating cancer or chronic rheumatoid arthritis in subjects. In view of Tamamura et al (Bioorg. Med. Chem., 1998, 6: 231-238) and in view of Tamamura et al (BBRC, 1998, 253(3): 877-882) read on this invention. Tamamura et al teach T134 and T140 that comprise the formula X-DLys-Pro-Tyr-Arg-Cit-Cys-Arg (see p.232, figure 1 in Bioorg. Med. Chem., and p. 878, figure 1 in BBRC).

Election of Species

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

SEQ ID NOS: 11-68.

Different diseases: cancer, breast cancer, prostate cancer, and chronic rheumatoid arthritis.

CXCR4 antagonists.

Each Group is patentably distinct due to structural differences. For any Group selected, the Applicants are required to elect a single disclosed species from SEQ ID

NOS 11-68, single disclosed disease and single disclosed CXCR4 antagonist. For example, if Group 10 is selected, the Applicants are to elect a single disclosed species from SEQ ID NOs 11, 15, 21, 25, 27, 31, 59, 60, 61, 62, or 64 and a single disclosed species of cancer and a single disclose CXCR4 antagonist. If Group 20 is selected, the Applicants are to elect a single disclosed species from SEQ ID NOs 14, 28, 30 or 24 and a single disclosed CSCR4 antagonist.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The claims are deemed to correspond to the species listed above in the following manner:

Claims 14, 18, 23-32, and 33-40.

The following claim(s) are generic: 1-3, 5, 7-10, 15, 17.

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: SEQ ID NOS 11-68 contain different amino acids and N- and C-terminal compounds that make each peptide patentably distinct one from the other. Different amino acids and N- and C-terminal

derivations give each peptide different structure. Search for one would not lead to the other. Different disease, cancer, breast cancer, prostate cancer and chromic rheumatoid arthritis are patentably distinct diseases. Treatment for cancer would not treat rheumatoid arthritis, and treatment for one cancer would not work for the other. CXCR4 antagonists have different structures, therefore, patentably distinct.

7. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

9. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of

record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusions

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982. The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Julie Ha
Patent Examiner

2/5/07
ANISH GUPTA
PRIMARY EXAMINER